

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Himanshu BRAHMBHATT et al.

Title: PHARMACEUTICALLY

COMPATIBLE METHOD FOR

PURIFYING INTACT BACTERIAL MINICELLS

Appl. No.: 10/602,021

Filing Date: 6/24/2003

Examiner: Unassigned

Art Unit: 1744

<u>INFORMATION DISCLOSURE STATEMENT</u> <u>UNDER 37 CFR §1.56</u>

Mail Stop PATENT APPLICATION Commissioner for Patents PO Box 1450 Alexandria, Virginia 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

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TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

RELEVANCE OF EACH DOCUMENT

All of the documents are in English.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

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Respectfully, submitted

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Registration No. 29,768

MODIFIED PTO/SB/08 (08-00) Approved for use through 10/31/2002. OMB 0651-0031

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number. Substitute for form 1449B/PTO Complete if Known INFORMATION DISCLOSURE **Application Number** 10/602,021 STATEMENT BY APPLICANT **Filing Date** 06/24/2003 Himanshu BRAHMBHA **First Named Inventor** Date Submitted: March 16, 2004 **Group Art Unit** 1744 MAR 1 6 2004 (use as many sheets as necessary) **Examiner Name** Unassigned 1 of **Attorney Docket Number** 060348-0104 Sheet

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| | | U.S. Patent Document | | | Date of Publication of | Pages, Columns, Line's, Where Relevant |
| Examiner Initials* | Cite No. ¹ | Number | Kind Code ² (if known) | Name of Patentee or Applicant of Cited Document | Cited Document MM-DD-YYYY | Passages or Relevant Figures Appear |
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| FOREIGN PATENT DOCUMENTS | | | | | | | | |
|--------------------------|--------------------------|-----------------|-----------|--|---|--|--|----------------|
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| | A1 | wo | 03/033519 | A2 | BRAHMBHATT, Himanshu | 04-24-2003 | | |
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| | | NON PATENT LITERATURE DOCUMENTS | |
|-----------------------|--------------------------|--|----|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published. | T⁵ |
| | A2 | BRAHMBHATT, Cloning and Molecular Characterization of the rfb Gene Cluster from Salmonella typhimurium LT2, Thesis, University of Adelaide, S. Australia, July 1987 | |
| | А3 | Britton et al., "Characterization of a prokaryotic SMC protein involved in chromosome partitioning," Genes Dev., 1998, pp. 1254-1259, Vol. 12, Cold Spring Harbor Laboratory Press | |
| | A4 | Clark-Curtiss et al., Analysis of Recombinant DNA Using <i>Escherichia coli</i> Minicells, Methods in Enzymology, 1983, pp. 347-363, Vol. 101, Academic Press, NYC, USA | |
| | A5 | De Boer et al., Roles of MinC and MinD in the site-Specific Septation Block Mediated by the MinCDE System of Escherichia coli, Journal of Bacteriology, Jan. 1992, pp. 63-70, Vol. 174, No. 1, American Society for Microbiology | |
| | A6 | Dorward et al., Export and Intercellular Transfer of DNA via Membrane Blebs of <i>Neisseria gonorrhoeae</i> , Journal of Bacteriology, May 1989, pp. 2499-2505, Vol. 171, No. 5, American Society for Microbiology | |
| | A7 | Forbes, Crossflow Microfiltration, Australian Journal of Biotechnology, June 1987, pp. 30-33, Vol. 1, No. 1, National Library of Medicine | |

| Examiner | | Date | |
|-----------|--|------------|--|
| Signature | | Considered | |

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| | STATEMENT | BY APPLI | CANT | Filing Date | 06/24/2003 | | |
| | Data Cubmitta | J. 84b 46 | 2004 | First Named Inventor | Himanshu BRAHMBHATT | | |
| | Date Submitted | a: March Te | 5, 2004 | Group Art Unit | 1744 | | |
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| Sheet | 2 | of | 3 | Attorney Docket Number | 060348-0104 | | |

| _ | | NON PATENT LITERATURE DOCUMENTS | | | |
|-----------------------|-----|--|---|--|--|
| Examiner Initials* | | | | | |
| | A8 | Frazer et al., Production, Properties and Utility of Bacterial Minicells, Current Topics in Microbiology and Immunology, 1975, pp. 1-84, 69: 1, National Library of Medicine | | | |
| | A9 | Harlow et al., Cloning and Characterization of the <i>gsk</i> Gene Encoding Guanosine Kinase of <i>Escherichia coli</i> , Journal of Bacteriology, Apr. 1995, pp. 2236-2240, Vol. 177, No. 8, American Society for Microbiology | | | |
| | A10 | Harry, Bacterial cell division: regulating Z-ring formation, Molecular Microbiology, 2001, pp. 795-803, Vol. 40(4), Blackwell Science Ltd. | | | |
| | A11 | Hiraga et al., Chromosome Partitioning in <i>Escherichia coli</i> : Novel Mutants Producing Anucleate Cells, Journal of Bacteriology, Mar. 1989, pp. 1496-1505, Vol. 171, No. 3, American Society for Microbiology | | | |
| | A12 | Hu et al., Topological regulation of cell division in <i>Escherichia coli</i> involves rapid pole to pole oscillation of the division inhibitor MinC under the control of MinD and MinE, Molecular Microbiology, 1999, pp. 82-90, Vol. 34(1), Blackwell Science Ltd. | - | | |
| | A13 | Ireton et al., spoOJ Is Required for Normal Chromosome Segregation as well as the Initiation of Sporulation in Bacillus subtilis, Journal of Bacteriology, Sept. 1994, pp. 5320-5329, Vol. 176, No. 17, American Society for Microbiology | | | |
| | A14 | Katsui et al., Heat-Induced Blebbing and Vesiculation of the Outer Membrane of <i>Escherichia coli</i> , Journal of Bacteriology, Sept. 1982, pp. 1523-1531, Vol. 151, No. 3, American Society for Microbiology | | | |
| | A15 | Kihara et al., Analysis of a FliM-FliN Flagellar Switch Fusion Mutant of <i>Salmonella typhimurium</i> , Journal of Bacteriology, Aug. 1996, pp. 4582-4589, Vol. 178, No. 15, American Society for Microbiology | | | |
| | A16 | Levin et al., Identification of <i>Bacillus subtilis</i> Genes for Septum Placement and Shape Determination, Journal of Bacteriology, Nov. 1992, pp. 6717-6728, Vol. 174, No. 21, American Society for Microbiology | | | |
| | A17 | Matsuzaki et al., Interactions of an antimicrobial peptide, magainin 2, with outer and inner membranes of Gram-negative bacteria, BBA, 1997, pp. 119-130, Vol. 1327, Elsevier Science B.V. | | | |

| Examiner Signature | Date Considered | |
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| | A18 | Okada et al., Possible function of the cytoplasmic axial filaments in chromosomal segregation and cellular division of <i>Escherichia coli</i> , Science Progress, 1993/94, pp. 253-264, Vol. 77(3/4), | |
| | A19 | Okada et al., Cytoplasmic Axial Filaments in <i>Escherichia coli</i> Cells: Possible Function in the Mechanism of Chromosome Segregation and Cell Division, Journal of Bacteriology, Feb. 1994, pp. 917-922, Vol. 176, No. 3, American Society for Microbiology | |
| | A20 | Raskin et al., MinDE-Dependent Pole-to-Pole Oscillation of Division Inhibitor MinC in <i>Escherichia coli</i> , Journal of Bacteriology, Oct. 1999, pp. 6419-6424, Vol. 181, No. 20, American Society for Microbiology | |
| | A21 | Reeve, Use of Minicells for Bacteriophage-Directed Polypeptide Synthesis, Methods in Enzymology, 1979, pp. 493-503, Vol. 68, Academic Press, NYC, USA | |
| | A22 | Reeve et al., Bacteriophage SPO1-Induced Macromolecular Synthesis in Minicells of <i>Bacillus subtilis</i> , Journal of Bacteriology, June 1975, pp. 1308-1316, Vol. 15, No. 6, American Society for Microbiology | |
| | A23 | Sancar et al., Simple Method for Identification of Plasmid-Coded Proteins, Journal of Bacteriology, Jan. 1979, pp. 692-693, Vol. 137, No. 1 | |
| | A24 | Stewart et al., Genetic and Morphological Characterization of an <i>Escherichia coli</i> Chromosome Segregation Mutant, Journal of Bacteriology, July 1992, pp. 4513-4516, Vol. 174, No. 13, American Society for Microbiology | |
| | A25 | Wachi et al., New <i>mre</i> Genes <i>mreC</i> and <i>mreD</i> , Responsible for Formation of the Rod Shape of <i>Escherichia coli</i> Cells, Journal of Bacteriology, Dec. 1989, pp. 6511-6516, Vol. 171, No. 12, American Society for Microbiology | |

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